UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/462,355	06/05/1995	ROGER COLEMAN	PF-0040-US	7494

7590 04/25/2002

BARBARA J LUTHER
INCYTE PHARMACEUTICALS
3174 POTER DRIVE
PALO ALTO, CA 94304

EXAMINER
ULM, JOHN D

ART UNIT	PAPER NUMBER
1646	20

DATE MAILED: 04/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/462,355	Coleman et al.
Examiner	**Art Unit**
John Ulm	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 13, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *12-22* is/are pending in the application.

4a) Of the above, claim(s) *18-22* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *12-17* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *14*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

1) Claims 12 to 22 are pending in the instant application. Claims 12 to 15 and 17 have been amended and claims 18 to 22 have been added as requested by Applicant in Paper Number 19, filed 13 February of 2002.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Newly submitted claims 18 to 22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The isolated polynucleotide of claims 12 to 17 and the process of claims 18 to 22 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of claims 12 to 17 can be employed in the production of a protein, which is a process that is materially different from the detection method of claims 18 to 22. Further, claims 18 to 22 are not limited to a process which employs a polynucleotide of claims 12 to 17.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the

merits. Accordingly, claims 18 to 22 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

5) Claims 12 to 17 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 5 of Paper Number 17.

Applicant argues that the claimed polynucleotides encode proteins which are useful as tools for toxicology testing, drug discovery, and the diagnosis of disease and that these uses are "well-established" and "specific". It is noted that toxicology testing and drug discovery are not specifically recited in the specification as originally filed. Each of the alleged uses in toxicology testing, drug discovery, and the diagnosis of disease will be addressed individually, because the facts and issues directed to each use are distinct and separable.

First, Applicant argues that toxicology testing is a well-established utility and concludes that any naturally occurring polypeptide, including those polypeptides which are bound by the antibodies encompassed by the instant claims, could be used in this manner and that the claimed invention possesses specific and substantial utility in this capacity. However, for a utility to be "well-established" it must be specific, substantial and credible. In this case, as conceded by Applicant, all naturally occurring polypeptides are in some combination useful in toxicology testing. It is noted that the particulars of toxicology testing with SEQ ID NO:2 are not disclosed in the instant specification. Neither the toxic substances nor the susceptible organ systems are identified. Further, Applicant has failed to identify the consequences of identifying a compound

which is toxic to a polypeptide encoded by the claimed polynucleotide. It is well known that excessive concentrations of common compounds such as sodium chloride and ethanol are toxic to humans. Applicant has not disclosed the practical benefit of determining the toxic (denaturing) concentration of a compound such as sodium chloride or ethanol on a polypeptide encoded by a polynucleotide of the instant invention. If one does not know the effects that the denaturation of a protein of the instant invention will have on an individual then a knowledge of the minimal concentration of sodium chloride or ethanol which is required to denature that protein is of no immediate practical benefit. Toxicology testing is a general utility which would apply to virtually every member of a general class of materials, such as any collection of proteins or DNAs, but, it is not a specific utility with respect to SEQ ID NO:2 because the consequences of denaturing that particular protein are not disclosed, and toxicology testing does not constitute a "well-established" utility.

Applicant urges that the claimed polynucleotides can be employed in a disease diagnostic process. Because any potential diagnostic utility is not yet known and has not yet been disclosed, the utility is not substantial because it is not currently available in practical form. The instant specification does not identify even a single disease or disorder with which a protein comprising the amino acid sequence of SEQ ID NO:2 has been credibly associated. Moreover, use of the claimed polynucleotide in an array for toxicology screening is only useful in the sense that the information that is gained from the array is dependent on the pattern derived from the array, and says nothing with regard to each individual member of the array. Again, this is a utility which

would apply to virtually ever member of a general class of materials, such as any collection of proteins or DNAs. Even if the expression of Applicant's individual protein is affected by a test compound in an array for drug screening, the specification does not disclose any specific and substantial interpretation for the result, and none is known in the art. Given this consideration, the individually claimed antibody has no "well-established" use. The artisan is required to perform substantial further experimentation on the claimed material itself in order to determine to what "practical use" any expression information regarding this polynucleotide could be put.

The employment of a protein of the instant invention, or a polynucleotide which encodes that protein, in toxicology testing is not a substantial and specific utility. As conceded by Applicant, all human proteins can be employed in such a process irrespective of their normal function. Such utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility.

One could just as readily argue that any purified compound having a known structure, such as the steroid compound which was the subject of the *Brenner v. Manson* decision cited above, could be employed as an analytical standard in such processes as nuclear magnetic resonance (NMR), infrared spectroscopy (IR), and mass spectroscopy as well as in polyacrylamide gel electrophoresis (PAGE), high performance liquid chromatography (HPLC) and gas chromatography. None of these important processes could be practiced without either calibration standards having known molecular structures or, at least, a range of molecular weight markers having known molecular weights. One could further extrapolate upon this premise by

asserting that any item having a fixed measurable parameter can be employed to calibrate any machine or process which measures that parameter. For example, any item having a constant mass within an acceptable range can be employed to calibrate a produce scale in a grocery store. The calibration of produce scales is certainly an important function since most states require produce scales to be calibrated and certified. Therefore, to accept Applicant's arguments that any nucleic acid encoding any protein of human origin is useful in a toxicology test would be comparable to conceding that any object of fixed mass has *prima facie* utility as a weight standard, irrespective of any other properties possessed by that object. It was just such applications that the court appeared to be referring to when it expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)). Because the steroid compound which was the subject of that decision had a known structure and molecular weight it could have readily been employed as a molecular standard at that time. Further, because that compound was a hydrocarbon it certainly could have been employed in the well known process of combustion for purposes of lighting and/ or the generation of heat. The generation of heat by combustion of hydrocarbons certainly was and remains an important process. Irrespective of such obvious utilities, the court still held that the compound produced by the process at issue in *Brenner v. Manson* did not have a specific and substantial utility.

To grant Applicant a patent encompassing a polynucleotide which encodes a naturally occurring human protein of as yet undetermined biological significance based upon Applicant's

assertion that any human protein is useful in toxicology testing would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" *Brenner v. Manson, Ibid*). To grant Applicant a patent on the claimed polynucleotide based solely upon an assertion that the protein encoded thereby can be employed in toxicology testing is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted and would be no different than granting a patent on the process disputed in *Brenner v. Manson* on the premise that the steroid produced thereby was useful as an analytical standard or as a combustible fuel source.

Applicant's arguments that the "REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS" "Misstate the Law" will not be answered by the examiner. The contents of 35 U.S.C., 37 C.F.R., judicial decisions, and guidelines established by the USPTO are not subject to examiner review and will not be questioned or defended by the examiner. These are decisions made by legally empowered government entities to which the examiner is subordinate and those decisions will be followed without question by the examining corps.

6) Claims 12 to 17 stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7) Applicant's arguments filed 13 February have been fully considered but they are not persuasive for those reasons given above.

8) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800